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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/050,366 03/31/98 JOHANSSON

G 0151/00211

EXAMINER

MOEZIE, F

ART UNIT

PAPER NUMBER

1653

14

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/050,366

Applicant(s)

Johannsson

Examiner

F. Moegle

Group Art Unit

1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 mos. MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 19-40 is/are pending in the application.
- Of the above claim(s) 25, 26, 31-40 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 19-24, 27-30 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 19-40 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Serial Number: 09/050,366

Art Unit: 1654

SUMMARY OF ACTIONS

In the response to the restriction requirement set forth in the Office Action mailed 05 February 1999, paper no. 6, applicant elected claims drawn to insulin related medicaments and methods of treating, paper no. 7, filed 25 February 1999.

In the response filed 19 July 1999, paper no. 11; Original claims 1-18 were canceled and new claims 19-40 were substituted instead. The new claims were again subjected to Restriction Requirement and Specie Election, Office action mailed October 13 1999, paper no. 13.

In response to the Office action mailed 13 October 1999, applicant elected Group II invention, claims 19-24 and 27-30, without traverse, in paper no. 11, filed 19 July 1999. Applicant failed to elect a specie of GH analog, hence the GH in claim 19 will be considered as the elected specie in this Office action.

Claims 19-24 and 27-30 are examined on their merits in this Office action insofar as they are readable on the elected invention, ie, insulin related conditions.

Claims 25, 26 and 31-40 are withdrawn from further consideration by the examiner as being drawn to non-elected inventions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1654

Claims 19-24 and 27-30 are objected to as having the non-elected subject matter or being dependent from the claim(s) containing non-elected subject matter. Deletion of the non-elected subject matter from the claims is suggested.

REJECTION - 35 USC 112, 1ST and 2ND PARAGRAPH

New claims 22-24, 28 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a patient having NIDDM, does not reasonably provide enablement for preventing a normal person from acquiring NIDDM. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no evidence that an individual would develop resistance to acquiring NIDDM. The hosts being treated are distinctly different in each case, i. e., a healthy subject vs a diabetic patient.

Claim 20 is rejected under 35 USC 112, 2nd paragraph as being indefinite because it lacks antecedent basis for the term "functional analog thereof" in claim 19 from which it depends. Furthermore, the term "grown hormone" at line 1 of the claim is incorrect.

REJECTION - 35 USC 102 and 103 (a)

New claims 19-21 are rejected under 35 USC 102 (b) as being anticipated by Sonksen et al.

Serial Number: 09/050,366

Art Unit: 1654

The reference discloses treating diabetic patients with growth hormone to minimize the risk of getting hypoglycemia resulting from the use of insulin. The reference teaches that *"Hypoglycemia can occur at any time in an insulin-treated diabetic subject, --- Hypoglycemic unawareness is a serious and still unsolved clinical problem in some insulin-dependent diabetic patients."* col 1, lines 54-60.

Because insulin is used to treat diabetic patients which results in developing a hypoglycemic condition, to minimize the risk of developing hypoglycemia - growth hormone is used. The problem of developing hypoglycemia, however, is greater in some IDDM patients, according to the reference. Therefore, the claims are anticipated by the art.

The new claims 19-24 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonksen et al.

The reference teaches that hypoglycemia can be treated in diabetic patients using hGH. The reference does not *show* treating the NIDDM patients with GH.

An ordinary art skilled at the time the invention was made would have reasonably expected to successfully treat a patient having diabetes (IDDM or NIDDM) with GH or analogs thereof according to the teachings of the reference. However, the success rate would have been expected to be greater for NIDDM patients as compared with IDDM patients - in view of the reference's teachings.

Art Unit: 1654

RESPONSE TO REMARKS

Applicant's remarks filed 19 July 1999, paper no. 13, have been fully considered and found persuasive in-part.

The specification remains objectionable because the format of the specification is not in compliance with the accepted USPTO format. See the recommended format in the earlier Office action. The section on "The Brief Description of the Drawings" should appear following the "Brief Summary of the Invention". Moreover, heading for the "Detailed Description of the Invention" is missing from the specification.

The earlier rejection of claims 1, 2, 4, 5, 12, and 13 (now canceled) under 35 USC 101 is withdrawn in view of the amendments, paper no. 11.

New claims 19-21 are rejected under 35 USC 112, 1st paragraph as lacking enablement for "preventing" insulin resistance and the use of "GH analogs" in the method for treating, for the reasons set forth above under the same ground of rejection.

The earlier rejection of the claims under 35 USC 102 (b) over Sonksen et al patent is maintained for the reasons of record and the argument cited above. All of the limitations of the claims are disclosed for the above claims since the patients being treated are just insulin sensitive (IDDM or NIDDM) patients.

Art Unit: 1654

New claims 19-24 and 27-30 are rejected under 35 USC 103 (a) over Sonksen et al for the reasons of record and the reasons set forth herein above under both grounds of rejection. The reference discloses that "Hypoglycemic unawareness is a serious and still unsolved clinical problem in some insulin-dependent diabetic patients" col. 1, lines 58-60. Apparently, this problem is not as acute in patients having NIDDM. Mere allegation of unexpected results (page 6 of remarks) is insufficient to overcome this ground of rejection.

Remarks regarding the common sense interpretation for "a functional analog thereof" has been considered, but not found persuasive. The term fails to set forth a) the nature of the analog (peptide or non-peptide) and b) the intended function.

The inadvertent omission of the figures have been noted, however a verified form of the figures would have to be submitted to complete the instant file disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Serial Number: 09/050,366

Page 7

Art Unit: 1654

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 19-24 and 27-30 are not allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. Christopher Low (SPE) at 308-2923.

F.T. Moezie
F.T. MOEZIE, P.H.
PRIMARY EXAMINER
ART UNIT 1653

Art Unit: 1654

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